

**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph Kim on November 10, 2010.

Claim 1 was amended as follows:

--Claim 1. A method for inspecting in vivo migration of fat-soluble vitamins and/or fat-soluble food factors in a body of a subject, comprising analyzing fat-soluble vitamins and/or fat-soluble food factors in parotid saliva collected from the subject, wherein the fat-soluble vitamins and/or fat-soluble food factors are positively detected in the parotid saliva.--

Claim 2 was amended as follows:

--Claim 2. A method for inspecting in vivo migration of fat-soluble vitamins and/or fat-soluble food factors contained in ingested health supplements, drugs or foods into a body of a subject, comprising analyzing fat-soluble vitamins and/or fat-soluble food factors in parotid saliva collected from the subject, wherein the fat-soluble vitamins and/or fat-soluble food factors are positively detected in the parotid saliva.--

Claim 3 was amended as follows:

--Claim 3. The method according to claim 2, wherein the inspecting is conducted by comparing the concentrations of the fat-soluble vitamins and/or fat-soluble food factors in the parotid saliva of the subject after ingestion of the health supplements, drugs or

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foods with either the concentrations of the fat-soluble vitamins and/or the fat-soluble food factors in the parotid saliva of the subjects before ingestion of the health supplements, drugs or foods, or by comparing with the mean concentrations of the fat-soluble vitamins and/or the fat-soluble food factors in the parotid saliva of a control group ingesting no health supplements, drugs or foods.--

Claim 4 was amended as follows:

--Claim 4. A method for inspecting effect or action of an administered therapeutic agent on in vivo biosynthesis and metabolism of fat-soluble vitamins and/or fat-soluble food factors in a subject, comprising

analyzing fat-soluble vitamins and/or fat-soluble food factors in parotid saliva collected from the subject as indicators, wherein the fat-soluble vitamins and/or fat-soluble food factors are positively detected in the parotid saliva, and wherein an increase or decrease in the amount of the vitamins or food factors in the parotid saliva of the subject after being administered with a therapeutic agent compared with either the concentrations of the fat-soluble vitamins and/or the fat-soluble food factors in the parotid saliva of subjects the subject before taking the therapeutic agent, or compared with the mean concentrations of the fat-soluble vitamins and/or the fat-soluble food factors in parotid saliva of a control group not having taken the therapeutic agent determines the effect of the therapeutic agent on the in vivo biosynthesis and metabolism of the vitamins and/or food factors in the subject.

Claim 7 was amended as follows:

--Claim 7. A method for assessing suitability for administering or dosing a therapeutic agent having effect or action on biosynthesis and metabolism of fat-soluble vitamins and/or the fat-soluble food factors comprising carrying out the method according to claim 4, and determining whether to ingest the health supplements, drugs or foods comprising fat-soluble vitamins and/or fat-soluble food factors therapeutic agent based on the results.--

Claim 13 was amended as follows:

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--Claim 13. The method according to claim 1, comprising:

- (a) extracting collected parotid saliva from an absorber with absorbed parotid saliva, and/or from a preservative solution with preserved absorber with a containing an absorber with absorbed parotid saliva using a water-soluble organic solvent, a hydrocarbon base organic solvent, or a mixture of isopropanol and ethyl acetate,
- (b) separating the fat-soluble vitamins and/or the fat-soluble food factors from the extract by high-performance liquid chromatography, and
- (c) detecting the separated fat-soluble vitamins and/or the fat-soluble food factors.--

Claim 15 was amended as follows:

--Claim 15. A method for screening drugs, [[or]] health supplements, or foods comprising carrying out the method according to claim 1, and determining whether to ingest the health supplements, drugs or foods comprising fat-soluble vitamins and/or fat-soluble food factors based on the results.--

Claim 16 was amended as follows:

--Claim 16. A method for assessing suitability of ingestion or [[an]] intake of health supplements, drugs or foods comprising fat-soluble vitamins and/or fat-soluble food factors, comprising carrying out the method according to claim 3, and determining whether to ingest the health supplements, drugs or foods comprising fat-soluble vitamins and/or fat-soluble food factors based on the results.--

Claim 17 was canceled.

Claim 18 was amended as follows:

--Claim 18. The method according to claim 12, comprising:

- (a) extracting the collected parotid saliva [[,]] from the absorber with the absorbed parotid saliva, and/or from the preservative solution with the preserved absorber with containing the absorber with absorbed parotid saliva using a water-soluble organic solvent, a hydrocarbon base organic solvent, or a mixture of isopropanol and ethyl acetate,

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- (b) separating the fat-soluble vitamins and/or the fat-soluble food factors from the extract by high-performance liquid chromatography, and
- (c) detecting the separated fat-soluble vitamins and/or the fat-soluble food factors.--

Claim 20 was amended as follows:

--Claim 20. A method for screening drugs, [[or]] health supplements or foods, comprising carrying out the method according to claim 14, and determining whether to ingest the health supplements, drugs or foods comprising fat-soluble vitamins and/or fat-soluble food factors based on the results.--

2. The following is an examiner's statement of reasons for allowance: Application serial no. 10/598,297 is being allowed in view of the English language translations of the Japanese foreign priority documents, the declaration filed under 37 CFR 1.132, and since none of the prior art of record teaches or fairly suggests a method for inspecting the in vivo migration of fat-soluble vitamins and/or fat soluble food factors in the body of a subject by analyzing the fat soluble vitamins and/or fat soluble food factors in parotid saliva collected from the subject, wherein a positive amount of the vitamins and/or food factors are detected in the parotid saliva. The instant invention differs from the closest prior art to Lumikari et al (cited in the Office action mailed on June 22, 2010) since Lumikari et al teach that fat soluble vitamins and/or food factors cannot be detected in parotid saliva, whereas the instant invention uses a methodology where fat soluble food factors and vitamins can be detected in parotid saliva as a means for detecting the in vivo migration of the food factors and/or vitamins through the body of a subject.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1777

mmw

November 12, 2010

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1777

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